



IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

APPLICANT: Takeda Pharmaceutical Co., Ltd.
U.S. PATENT NO. 6,462,058
ISSUED: October 8, 2002
TO: FUJISHIMA ET AL.
FOR: BENZIMIDAZOLE COMPOUND
CRYSTAL
FROM: Serial No. 09/674624
FILED: June 15, 2000
EXTENSION FILED: March 26, 2009
ATTORNEY 04164.0012USTE
DOCKET NO.

DATE: October 2, 2009

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this paper is being mailed to the U.S. Patent and Trademark Office on October 2, 2009.

By: *Justine Suleski*
Name: Justine L. Suleski

SUBMISSION OF SUPPLEMENTAL INFORMATION
UNDER 37 C.F.R. § 1.765

Mail Stop: Patent Extension
Commissioner of Patents
Patent Extension
P.O. Box 1450
Alexandria, Virginia 22313-1450

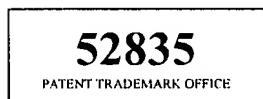
Dear Sir:

Applicant Takeda Pharmaceutical Co., Ltd. hereby submits a copy of relevant pages of Orange Book database of the Food and Drug Administration that indicates that pediatric exclusivity has been allowed to U.S. Patent No. 6,462,058 by the Food and Drug Administration available at

http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=022287&TABLE1=OB_Rx,
http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=022287&Product_No=001&table1=OB_Rx and
http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=022287&Product_No=002&table1=OB_Rx. The pediatric exclusivity to the ‘058 patent was allowed based on the pediatric exclusivity granted to patents relevant to PREVACID®, whose active ingredient is lansoprazole, which is a racemate of dexlansoprazole as described in section (4) on pages 3-4 of the application for extension filed on March 26, 2009.

Applicant respectfully contends that the pediatric exclusivity, which is based on a different statute from 35 U.S.C. § 156, such as § 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a), does not affect Applicant's eligibility for the patent term extension nor the length of the extension because 35 U.S.C. § 156 requires that the term of the patent have never been extended under § 156 (e)(1) and U.S. Patent No. 6,462,058 has never been extended under this section of 35 U.S.C.

Respectfully submitted,



HAMRE, SCHUMANN, MUELLER &
LARSON, P.C.
P.O. Box 2902
Minneapolis, MN 55402-0902
(612) 455-3800

Dated: October 2, 2009

By: Douglas P. Mueller
Reg. No. 30,300

DPM/my